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(to be used for all c			miner Name	Jeffrey	T. Palenil	k		
(to be used for all correspondence after initial filing)  Total Number of Pages in This Submission 7			rney Docket Number	<del></del>	RO4246US (#90568)			
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Date July 21, 2008			Reg. No. 24,603					
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

PTO/SB/17 (10-07)

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Effective on 12/08/2004. Complete if Known drsuant to the Consolidated Appropriations Act, 2005 (H.R. 4818). **Application Number** 10/580,485 TRANSM Filing Date May 24, 2006 For FY 2008 Joachim Moormann First Named Inventor **Examiner Name** Jeffrey T. Palenik X Applicant claims small entity status. See 37 CFR 1.27 Art Unit 1615 TOTAL AMOUNT OF PAYMENT 0.00Attorney Docket No. RO4246US (#90568) METHOD OF PAYMENT (check all that apply) |X|<sub>None</sub> Check Credit Card Money Order Other (please identify): 08-2441 X Deposit Account Deposit Account Number:\_ Deposit Account Name: D. Peter Hochberg Co., L.P.A. For the above-identified deposit account, the Director is hereby authorized to: (check all that apply) Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee Charge any additional fee(s) or underpayments of fee(s) Credit any overpayments under 37 CFR 1.16 and 1.17 WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. **FEE CALCULATION** 1. BASIC FILING, SEARCH, AND EXAMINATION FEES **FILING FEES SEARCH FEES EXAMINATION FEES** Small Entity Small Entity Small Entity Fees Paid (\$) Fee (\$) **Application Type** Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$) Utility 310 510 210 155 255 105 Design 210 105 100 130 50 65 210 Plant 105 310 155 160 80 310 620 Reissue 155 510 255 310 Provisional 210 0 105 0 Small Entity 2. EXCESS CLAIM FEES Fee (\$) Fee Description Fee (\$) 50 25 Each claim over 20 (including Reissues) 210 105 Each independent claim over 3 (including Reissues) 370 185 Multiple dependent claims **Multiple Dependent Claims Total Claims Extra Claims** Fee (\$) Fee Paid (\$) Fee Paid (\$) Fee (\$) HP = highest number of total claims paid for, if greater than 20. **Extra Claims** Fee (\$) Indep. Claims Fee Paid (\$) -3 or HP =HP = highest number of independent claims paid for, if greater than 3. 3. APPLICATION SIZE FEE If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). Number of each additional 50 or fraction thereof Total Sheets Extra Sheets Fee (\$) 130.00 (round up to a whole number) x - 100 = 0.00 Fees Paid (\$) Non-English Specification, \$130 fee (no small entity discount) Other (e.g., late filing surcharge): SUBMITTED BY

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Signature

Name (Print/Type) D. Peter Hochberg

Registration No.

(Attorney/Agent)

Telephone

24,603

216-771-3800

PTO/SB/17 (10-07)

Approved for use through 06/30/2010. OMB 0651-0032 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE ork Reduction Act of 1995 no persons are required to respond to a collection of information unless it displays a valid OMB control number Under the P Complete if Known Effective on 12/08/2004. ant to the Consolidated Appropriations Act, 2005 (H.R. 4818). 10/580,485 Application Number TRANSMITTAL May 24, 2006 Filing Date For FY 2008 Joachim Moormann First Named Inventor **Examiner Name** Jeffrey T. Palenik X Applicant claims small entity status. See 37 CFR 1.27 1615 Art Unit TOTAL AMOUNT OF PAYMENT 0.00RO4246US (#90568) Attorney Docket No. METHOD OF PAYMENT (check all that apply) Money Order X None Credit Card L Other (please identify): 08-2441 Deposit Account Name: D. Peter Hochberg Co., L.P.A. Deposit Account Deposit Account Number: For the above-identified deposit account, the Director is hereby authorized to: (check all that apply) Charge fee(s) indicated below Charge fee(s) indicated below, except for the filing fee Charge any additional fee(s) or underpayments of fee(s) Credit any overpayments under 37 CFR 1.16 and 1.17 WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038. **FEE CALCULATION** 1. BASIC FILING, SEARCH, AND EXAMINATION FEES **FILING FEES** SEARCH FEES **EXAMINATION FEES** Small Entity Small Entity Small Entity Fees Paid (\$) **Application Type** Fee (\$) Fee (\$) Fee (\$) Fee (\$) Fee (\$) Utility 310 155 510 255 210 105 210 100 130 Design 105 50 65 210 Plant 105 310 155 160 80 310 620 Reissue 155 510 255 310 Provisional 210 0 0 0 0 105 2. EXCESS CLAIM FEES Small Entity Fee (\$) Fee (\$) Fee Description 50 25 Each claim over 20 (including Reissues) 210

Each independent claim over 3 (including Reissues)				210	103
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3. APPLICATION SIZE FEE

Other (e.g., late filing surcharge):

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$260 (\$130 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

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Signature

Registration No. (Attorney/Agent)

Registration No. (Attorney/Agent)

Date Quie 21, 2008

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Date: 7/21/08

Sean Mellino

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Joach

Joachim Moormann, et al.

Serial No. :

10/580,485 / Conf. No. 2532

Filing Date

May 24, 2006

Examiner / Group Art Unit

Jeffrey T. Palenik / 1615

Title

ORAL FORMULATIONS OF DEOXYPEGANINE

AND THEIR USES

Attorney File

RO4246US (#90568)

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

## Reply to Office Action Issued July 2, 2008

## Dear Sir:

Claims 1-38 are pending in the instant application. The Examiner has concluded that restriction to one of the following two groups is necessary:

Group I - Claims 1-15 and 25-37, drawn to an oral dosage medicament containing deoxypeganine.

Group II – Claims 16-24 and 38, drawn to uses for cholinergic active substances.

The Examiner explains in the Office action that the inventions listed as Groups I

and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features since U.S. Patent No. 6,548,510 (Asmussen, et al.) teaches at column 2, lines 33-47, oral and transdermal pharmaceutical forms which controllably administer deoxypeganine or one of its pharmaceutically acceptable acid addition salts (e.g., hydrochloride or hydrobromide salt of deoxypeganine). The Examiner also states that the doses are further taught as comprising excipients, such as flow-improving agents, solvents, and oils, as well as comprising 0.7-50% by weight of free deoxypeganine.

The Applicants object to the instant restriction requirement, with traverse. It is respectfully submitted that the claims of Group I are directed to an orally administrable film-shaped medicament containing deoxypeganine and/or a deoxypeganine derivative. Claims 16 to 24 (Group II) pertain to the use of deoxypeganine or a deoxypeganine derivative for producing an oral, film-shaped medicament. Therefore, it is submitted that these two groups of claims pertain to the use of specific pharmaceutically active ingredients for manufacturing a specific medicament, namely, an orally administrable, film-shaped dosage form and to said medicament as such.

It is further submitted by the Applicants that, with respect to the "corresponding technical features in view of Asmussen, et al.," the prior art reference only briefly mentions pharmaceutical dosage form for oral, transdermal or otherwise parenteral administration, and proposes that desoxypeganine can be present in such dosage forms in the form of a pharmaceutically acceptable acid addition salt. Asmussen, et al. fail to provide any indication that oral administration forms may be present in the form of a

film. Moreover, it is submitted that the oral administration form in Asmussen, et al. only

pertains to conventional oral administration forms, such as tablets, capsules, lozenges, or

liquids. Without any detailed disclosure pertaining to oral, film-shaped dosage forms,

this characterization of the present invention appears to be sufficient to illustrate the

single inventive concept the claims of both groups share. It is submitted that this is not

contradicted by the fact that the claims directed to the medicament as such and the claims

pertaining to the use of the active ingredient contain features being specific for each claim

category and absent in the claims of the other category. Therefore, it is respectfully

submitted that the claims of Group I and Group II are linked by the same technical

features.

The Applicant hereby elects the claims of Group I (which consist of claims 1-15

and 25-37, drawn to an oral dosage medicament containing deoxypeganine) for further

prosecution on the merits thereof.

The Examiner is invited to call the undersigned if there are any remaining issues

to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

D. Peter Hochberg

Reg. No. 24,603

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